IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Charlottesville Division

RETRACTABLE TECHNOLOGIES, INC., Movant, v. INTERNATIONAL HEALTHCARE WORKER SAFETY CENTER, Respondent.	Misc. Case No. 3:11-mc-00028-NKM

RESPONDENT'S BRIEF IN SUPPORT OF ITS MOTION FOR RECONSIDERATION AND TO QUASH RTI's SUBPOENA

Respondent, The Rector and Visitors of the University of Virginia for and on behalf of its International Healthcare Worker Safety Center (the "Center"), a non-party in the underlying litigation, respectfully moves for reconsideration of this Court's Order entered June 30, 2011, and in accordance with Rules 26 and 45 of the Federal Rules of Civil Procedure, for an order quashing the overly broad, burdensome and harassing subpoena issued by Retractable Technologies, Inc. (RTI). RTI's subpoena seeks the disclosure of confidential research data that was provided to the Center under a promise of confidentiality. RTI's subpoena also exceeds the scope of permissible discovery from a non-party under Rule 26. The Court therefore should quash RTI's subpoena.

I. Preliminary Statement

The Center is not a party to the underlying litigation between RTI and Becton Dickinson in the Eastern District of Texas. The Center began as a program at the University in 1991 and only employs four staff. Neither the Center nor any of its employees has been retained as a consultant

or expert witness in this case and none of them has any intention of serving in either role. Nonetheless, RTI has served the Center with an overly broad and burdensome subpoena. RTI requests 56 sweeping categories of documents and electronically stored information spanning 20 years. Among other things, RTI requests production of the Center's confidential research database. RTI's subpoena is harassing and clearly violates Rule 45(c)(1), which requires "[a] party or attorney responsible for issuing and serving a subpoena [to] take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena." This is not the first time RTI has sought to drag the Center into its litigation campaign against its competitors. Indeed, RTI has a long history of attempting to co-opt the Center's legitimate and important research for RTI's own purposes.

II. The Center and Its Mission

The International Healthcare Worker Safety Center (the "Center") has been devoted to research on the epidemiology and prevention of healthcare worker exposures to bloodborne pathogens for more than two decades. The Center's Director, Dr. Janine Jagger, and colleagues published a landmark study in the New England Journal of Medicine in 1988 on the characteristics of medical devices causing needlestick injuries. That groundbreaking research was instrumental in the development of a new generation of safer medical devices.

In 1991, Dr. Jagger created the EPINet data collection device to provide healthcare facilities with a standardized program for tracking needlestick injuries and blood and body fluid exposures. It is now used by more than 1,000 healthcare facilities.

In 1992, Dr. Jagger established a voluntary confidential data-sharing network of healthcare facilities using the EPINet data collection device. Participating healthcare facilities annually send data to the Center that are merged into an aggregate database. In exchange for

their participation, the Center promises that the hospitals' data will remain confidential and will not be disclosed. The Center's confidential research database is the longest-standing database of healthcare workers' at-risk exposures to blood and body fluids in the United States. The Center's research publications regularly are accessed by healthcare workers, government agencies, medical products manufacturers, and many others for benchmarking and research purposes.[1]

The Center's confidential research database is the foundation of the Center's research and advocacy, providing important support for new policies to improve healthcare worker safety.

II. History of RTI's Abusive Discovery Requests

RTI's brief in support of its Motion to Compel (hereafter "RTI BR.") provides a substantially abbreviated history of its harassment of the Center through non-party discovery requests. Long before RTI issued the current subpoena to the Center – its ***third*** – the Center had made known its position regarding the confidentiality and relevance of its research database and other information to the underlying litigation between RTI and its business competitors.

A. RTI's First Subpoena

RTI issued its first subpoena to the Center's Director in December 2001. RTI's first subpoena sought 44 categories of documents from the Center including, but not limited to its confidential research data.

The Center objected to RTI's subpoena and to the production of its confidential research data, but produced 2,206 pages of non-confidential documents to RTI. See Ex. A. RTI did not move to compel additional documents from the Center or otherwise challenge the Center's objections. But RTI's principal, Tom Shaw, (a party plaintiff in the underlying action) thereafter called the Center's Director to berate her regarding the Center's research and wrongly accused

[1] In 2002, Dr. Jagger received one of the most prestigious awards in the United States, a MacArthur Foundation fellowship, awarded to individuals who have shown "extraordinary originality" and dedication in their professional pursuits.

her of unethical conduct. See Ex. B (Mar. 14, 2002 Statement of J. Jagger). In response, the University issued a cease and desist letter to Mr. Shaw's counsel. See Ex. C (Apr. 3, 2002 Ltr. of S. Davis).

B. RTI's Second Subpoena

RTI issued a second subpoena to the Center in November 2007. RTI's second subpoena sought 35 categories of documents from the Center including, but not limited to its confidential research data. The University again objected to the production of its confidential research data and other materials. See Ex. D. Moreover, the Center noted RTI's second subpoena violated Rules 26 and 45 in numerous ways including:

- Some of the same categories of information sought in the 2007 subpoena already were produced to RTI in response to its 2001 subpoena.
- In response to the 2001 subpoena, the Center informed RTI that the Center does not collect and therefore could not produce some categories of information. RTI's 2007 subpoena nonetheless sought these same categories of information, even though RTI knew the Center did not possess them.
- RTI's 2007 subpoena requested many categories of information to which the Center objected in 2001. RTI's 2007 subpoena made no effort to address the Center's previous objections or to otherwise reasonably tailor its requests to the issues in dispute or the time-frame at issue in the underlying litigation.

Notwithstanding its objections, the Center produced another 287 pages of non-confidential documents to RTI. See Ex. E. RTI did not move to compel production of the Center's confidential research data or otherwise challenge the Center's objections.

C. RTI's Third Subpoena

RTI issued the present subpoena (i.e., the ***third*** subpoena) to the Center in February 2011. In RTI's third subpoena, it requested 56 categories of documents from the Center. RTI again sought production of the Center's confidential research data. The 2001 subpoena was substantially similar to the previous two subpoenas and suffered the same defects.

In a series of telephone calls, counsel for the Center explained to RTI's counsel the Center's prior objections and directed RTI's counsel to the Center's prior objections and its prior production of non-confidential documents.

D. RTI's Motion to Compel

RTI moved to compel the Center to disclose its confidential research data and other documents requested in the 2001 subpoena. RTI claimed that the 56 categories of requested documents were relevant to the underlying action on "essentially three issues: (1) the efficacy of [Becton Dickinson's] safety syringes and needles in preventing needlestick injuries; (2) [Becton Dickinson's] false advertising; and (3) [Becton Dickinson's] influence with the Center." RTI Br. at 9. The Center's counsel contacted RTI's counsel and requested an extension of time in which to file an opposition to RTI's Motion. The Center's counsel explained that he was going to be out of the office for more than two weeks in connection with a conference and vacation. RTI's counsel agreed to extend the briefing schedule to allow the Center time in which to file an opposition when its counsel returned to the office. But before the Center's counsel returned to the office, the Court entered an Order on June 30 granting RTI's Motion to Compel. The Center respectfully requests reconsideration of that Order.[2]

[2] In retrospect, the Center's counsel should have filed an unopposed motion to extend the briefing schedule so that the Court would have had notice of the parties' agreement and could have considered allowing such an extension of the briefing schedule under Local Civ. Rule 11(c)(1).

For the reasons set forth below, the 56 categories of documents requested in RTI's subpoena are not relevant to the underlying action and the subpoena therefore should be quashed. RTI is not prejudiced by the Court's reconsideration of RTI's Motion to Compel or the Center's Motion to Quash because RTI already had agreed to extend the briefing schedule to allow the Center time in which to file its opposition. The Center therefore respectfully request that the Court reconsider the issues presented in RTI's Motion to Compel and the Center's Motion to Quash.

III. Argument and Authority

A. The Court Should Quash RTI's Subpoena for the Center's Confidential Research Data

More than one-third of RTI's requests in the subpoena (Requests 1-21) seek disclosure of the Center's confidential research database. Indeed, RTI characterizes the Center's confidential research database as "[t]he jewel at the heart" of its requests. RTI Br. at 9. But RTI's request for the Center's entire research database is misplaced. RTI's claim that the Center's data is relevant to the underlying action rests on RTI's incorrect assertion that the Center's confidential research database contains information relating to the manufacturer, brand and model of devices involved in needlestick injuries. RTI Br. at 10. But the Center's confidential research database ***does not contain this information***. The Center's database therefore is not relevant to the underlying action. Moreover, healthcare entities that voluntarily disclosed their sensitive data to the Center for research purposes did so based on a promise of confidentiality. The Center's database therefore should be accorded a high degree of protection from compelled disclosure in a case in which the Center is not even a party. The Court should quash RTI's requests for the Center's research data.

The Court should not compel production of the Center's confidential research data. Rule 45(c)(3)(B)(i) provides that a court may quash a subpoena that seeks disclosure of "confidential research." Federal courts long have recognized that confidential academic research deserves enhanced protection from compelled disclosure. See, e.g., Cusumano v. Microsoft Corp., 162 F.3d 708, 714 (1st Cir. 1998) ("[a]cademicians engaged in pre-publication research should be accorded protection commensurate to that which the law provides journalists."); Burka v. U.S. Dept. of Health & Human Servs., 87 F.3d 508, 519-21 (D.C. Cir. 1996); Richards of Rockford, Inc. v. Pacific Gas & Elec. Co., 71 F.R.D. 388, 389 (N.D. Cal. 1976) ("society has a profound interest in the research of its scholars, work which has the unique potential to facilitate change through knowledge"). In Cusumano, the First Circuit reasoned as follows:

> scholars . . . are information gatherers and disseminators. If their research materials were freely subject to subpoena, their sources likely would refuse to confide in them. As with reporters, a drying-up of sources would sharply curtail the information available to academic researchers and thus would restrict their output. Just as a journalist, stripped of sources, would write fewer, less incisive articles, an academician, stripped of sources, would be able to provide fewer, less cogent analyses.

Cusumano, 162 F.3d at 714.

These concerns are particularly important where, as here, the Center has promised confidentiality to its research participants. The Terms of Participation in the EPINet program promise confidentiality for the data provided by participating hospitals. "Each hospital is assigned a unique identifier; the names of individual hospitals do not appear in the EPINet™ database and [d]ata from the EPINet™ Research Group are presented only in aggregate form, such that it is not possible to identify data from an individual hospital." See Ex. F. In Richards, the court noted:

> [m]uch of the raw data on which research is based simply is not made available except upon a pledge of confidentiality. Compelled disclosure of confidential

> information would without question severely stifle research into questions of public policy, the very subjects in which the public interest is greatest.

Richards of Rockford, Inc., 71 F.R.D. at 389-90. Accord United States v. Doe, 460 F.2d 328, 333 (1st Cir. 1972) (acknowledging "an important public interest in the continued flow of information to scholars about public problems which would stop if scholars could be forced to disclose sources of such information."); Farnsworth v. Proctor & Gamble Co., 758 F.2d 1545, 1547 (11th Cir. 1985) (protecting confidential information where production "could seriously damage voluntary reporting"); Snyder v. Amer. Motors Corp., 115 F.R.D. 211, 215-16 (D. Ariz. 1987) (quashing subpoena to avoid "potential for a chilling effect on research"). These concerns are heightened because the Center relies on the hospitals' voluntary participation to supply their sensitive data to the Center. Moreover, hospitals can cease participating and can even remove their data from the Center's research database at any time which would substantially compromise the Center's ability to conduct further research. See Ex. F Terms of Participation (stating "[a] hospital participating in the EPINet™ Research Group may withdraw its participation at any time" and "may request to have all of its data removed from the database at any time").

In addition, the Center does not own the data RTI seeks to acquire by subpoena. Even though the participating hospitals share their data with the Center, those hospitals – not the Center – continue to own their data (i.e., it is not the Center's data to give to RTI). The Terms of Participation state:

> 7. Data files from participating hospitals are in the exclusive custody of the IHWSC/UVa. They will not be loaned, copied, or distributed to any other party. The data will be accessed only by the staff of the IHWSC/UVa, or an approved person under direct, visible supervision of a Center staff member. Each participating hospital retains ownership of its own data.

See Ex. F. Accordingly, if RTI wants hospital data, RTI should be required to issue subpoenas directly to the participating hospitals – not to the Center, a research entity with whom the

hospitals voluntarily have shared their sensitive data premised on the conditions of confidentiality and non-disclosure.[3] Importantly, RTI does not need the Center's confidential research data because it does not contain the data elements that are relevant to RTI's underlying action.

In seeking disclosure of the Center's confidential research data, RTI argues that "[i]dentifying which type . . . and brands . . . are involved in needlestick injuries is a critical part of determining which safety-engineered devices actually work to eliminate or minimize accidental needlestick injuries." RTI Br. at 5. RTI states that the EPINet form on which hospitals collect information contains a space for the collection of the "Brand/Manufacturer of Product" and "Model" of the device. See RTI Br. at 10 and RTI Ex. H at 2. But those data elements are for the convenience of the hospital in collecting comprehensive information about its incidents. RTI wrongly asserts that participation in the EPINet program "require[s] that the type and brand be reported" and that "EPINet is designed to collect that data." RTI Br. at 6. That is not true. The Center does not solicit brand, manufacturer or model information from its participating hospitals and those data elements do not exist within the Center's confidential research database.[4] RTI knows this.

RTI claims that "the Center collects such data from a network of scores of hospitals over a span of years." RTI Br. at 6. But RTI knows that is not true. The Center repeatedly has told

[3] RTI acknowledges that it already has pursued this course with respect to some hospitals; it therefore clearly has the capacity to do the same with respect to others for which it seeks data, rather than getting information second-hand from the Center. See RTI Br. at 10 ("Retractable Technologies has already gathered through discovery sharps injury data from some hospitals").

[4] More than 1,000 hospitals use the EPINet device to track their needlestick incidents, but fewer than 85 participate in voluntarily reporting data to the Center. Of those voluntarily reporting data to the Center, they do not report manufacturer, product or model information. By way of another example, the EPINet form also contains spaces for the hospital to record the first and last name of the injured healthcare worker. Like brand and model information, healthcare worker names also are not shared by the participating hospitals with the Center and are not contained in the Center's confidential research database.

RTI that it ***does not collect brand or product data***. See Ex. A at 4 (stating "the Center does not actively solicit "brand-specific data"); Ex. D at 2 ("In response to the 2001 subpoena, the Center informed RTI that the Center does not collect and therefore cannot produce some categories of information. RTI's new subpoena seeks the same categories of information, even though RTI knows the Center does not possess them."), at 6 (Objecting to RTI's second subpoena requesting "Brand/Manufacturer of Product" data and stating "as the Center informed RTI in 2001, 'the Center does not solicit brand-specific data.'"), and at 9, 10, 11, 12, 20 and 21 (same). Indeed, the Terms of Participation makes clear that "[a]ll individual identifiers, brand names of products, and information related to follow-up of exposed or injured workers are deleted from data transmitted to the IHWSC/UVa, and do not appear in the EPINet™ database." See Ex. F.[5]

In short, the Center's confidential research database does not contain the data elements that arguably would be relevant to the underlying action – i.e., brand, product, and model of the devices – that RTI seeks. Even if the database had some tangential relevance to the underlying litigation – which it does not – it should be protected from disclosure because it is a confidential research tool that has been created by the Center for more than 20 years based on promises of confidentiality to program participants. The Court therefore should quash RTI's subpoena requesting the Center's confidential research database.

B. The Court should quash RTI's Requests Relating to Becton Dickinson's relationship with the Center

RTI suggests a nefarious link between the Center and Becton Dickinson. RTI claims that the "Center is funded by the Defendant in the underlying action." RTI Br. at 2. But that unqualified statement is not correct. In fact, the Center is an independent research center at the University of Virginia that receives funding from a variety of external sources – not an arm of or

[5] RTI acknowledges in its brief that "the Center regularly publishes information about needlestick injuries; however, these publicly released reports do not include make, model, or brand data." RTI Br. at 6.

a front for Becton Dickinson. While the Center has received funding from Becton Dickinson, it has received far more funding from other external sources. From the Center's organization in 1991 to the present, the Center has received more than two-thirds of its funding from outside sources other than Becton Dickinson – including competitors of Becton Dickinson.[6] Moreover, as RTI knows, the Center has a policy regarding its collaboration with industry that prevents Becton Dickinson (and the other companies who help fund the Center's work) from exercising control over the Center's activities. See Ex. G. The Center's policy states that "Center staff do not participate in activities related to the commercialization of specific products" and "avoid participating as expert witnesses, or in any other way, in litigation related to the safety of medical products." Id. That is, the Center does not compromise its role in promoting the use of safety products generally, by advocating one manufacturer's products over another's.

The Center and its research are not on trial here. Indeed, RTI fails to demonstrate that the Center's research has any relevance to the underlying action. On the contrary, the Center's position with respect to the relevance of its confidential research database has been consistent for more than 10 years. Thus, RTI's conspiracy theories relating to Becton Dickinson's alleged "influence on the Center" likewise are irrelevant. Even if the Center was wholly or majority funded by Becton Dickinson – which is not the case – that would not change the fact that the Center and its research data are not relevant to RTI's claims in the underlying lawsuit. RTI's subpoena is nothing more than a fishing expedition to rummage through the entirety of Center's records without any colorable justification or relevance to the underlying action.

[6] In addition to this external funding, Becton Dickinson also has endowed a position at the Center. But Becton Dickinson's is not the only endowed position at the Center, nor is it the largest endowed position. Another company has funded a faculty position at the Center with a larger endowment than the one created by Becton Dickinson.

C. The Court Should Quash RTI's Requests for All of Center's Speeches and Presentations

RTI argues that it should receive copies of virtually all of the Center's speeches and presentations for the past 20 years (Requests 48-49). RTI claims that its allegations in the underlying action include a claim that it has been excluded from certain conferences. RTI Br. at 13. But that is not what RTI requests from the Center. Rather, RTI seeks the production of every presentation and speech the Center has given in its 20-year existence. There is a profound disconnect between RTI's requests and its justification for them.

RTI also argues that these documents are relevant because some experts or witnesses have "acknowledged the expertise of the Center's personnel." RTI Br. at 13. First, as noted above, the production of every speech and presentation by the Center's personnel is not limited to the issue RTI claims justifies its request. Second, to the extent a witness has relied on a particular article or presentation – which RTI does not allege or demonstrate in its papers – only that particular article or presentation would be relevant – not the wholesale production of every speech and presentation made by the Center's personnel during the past 20 years.

IV. Conclusion

In short, the Center, a non-party to the underlying litigation, repeatedly has responded to RTI's fishing expeditions for documents and previously has produced to RTI approximately 2,500 pages of documents (without any reimbursement for the time and costs incurred in those productions). Further document productions or discovery from the Center are not only irrelevant to the underlying litigation, but also overly burdensome and unreasonable. Moreover, the forced disclosure of confidential research data entrusted to the Center under conditions of confidentiality seriously jeopardizes the Center's ability to persuade hospitals to continue participating in the data-sharing program and to voluntarily furnish their sensitive and

confidential data to the Center. Thus, such a disclosure threatens the Center's ability to continue conducting meaningful and important research in this area – as it has done for more than 20 years. Accordingly, for the reasons stated above, the Center respectfully requests that this Court reconsider and set aside its Order dated June 30, 2011 and enter an order quashing RTI's subpoena.

Date: July 14, 2011

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of July, 2011, a true and exact copy of the foregoing RESPONDENT'S BRIEF IN SUPPORT OF MOTION FOR RECONSIDERATION AND TO QUASH RTI'S SUBPOENA was served by electronic service pursuant to CM/ECF system to:

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